



Medical Necessity Criteria for Antidepressants I

Background

Antidepressants I (AD1s). This drug class includes all antidepressants except tricyclic antidepressants and monoamine oxidase inhibitors. The combination product Symbyax, which contains fluoxetine and the atypical antipsychotic olanzapine, was also excluded. After evaluating the relative clinical and cost effectiveness of medications in this class (the AD1s), the DoD P&T Committee recommended that the following medications be designated as non-formulary. This recommendation has been approved by the Director, TMA.

- Selective Serotonin Reuptake Inhibitors: escitalopram (Lexapro), fluoxetine 90-mg capsules (Prozac Weekly), fluoxetine in special packaging for the treatment of premenstrual dysphoric disorder (Sarafem), paroxetine controlled release (Paxil CR)
- Serotonin Norepinephrine Reuptake Inhibitors: desvenlafaxine (Pristiq), duloxetine (Cymbalta), bupropion HBr (Aplenzin)

Effective Date: 14 April 2010

Patients currently using a nonformulary antidepressant may wish to ask their doctor to consider a formulary alternative.

Special Notes:

1. Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.
2. MTFs will be able to fill non-formulary medications only if both of the following conditions are met: 1) the prescription must be written by an MTF provider; MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred AND 2) MN is established.
3. Fluvoxamine and trazodone are not typically considered to be therapeutic alternatives to other medications in this class, due to differences in the use of these products. Fluvoxamine, a SSRI, is FDA-approved for the treatment of obsessive compulsive disorder (OCD), but not depression. Trazodone, while FDA-approved for the treatment of depression, is more commonly used as an adjunctive (add-on) medication to treat symptoms of insomnia in patients treated with other antidepressants. Both are generically available

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All current and new users of non-formulary antidepressants must meet one of the following criteria in order for medical necessity to be approved:

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Pristiq – The non-formulary cost share for Pristiq may be reduced to the formulary cost share if the patient meets any of the following criteria:

1. Use of the formulary SNRI (venlafaxine) is contraindicated (e.g., hypersensitivity to a dye or other inert ingredient) and use of any other formulary antidepressant is not clinically appropriate.

2. The patient requires treatment with an SNRI (e.g., due to failure of SSRI therapy), has experienced adverse effects with venlafaxine, and would not be expected to experience adverse effects with Pristiq.
3. The patient has previously responded to Pristiq, and changing to a formulary medication would incur unacceptable risk (e.g., the patient is currently stabilized on therapy with Pristiq and changing to a formulary medication would present a risk of destabilization).

Prozac Weekly, Sarafem, - The non-formulary cost share for Prozac Weekly and Sarafem may be reduced to the formulary cost share if the patient meets either of the following criteria:

1. Use of the formulary product is contraindicated (e.g., hypersensitivity to a dye or other inert ingredient), treatment with the non-formulary product is not contraindicated, and use of other formulary antidepressants is not clinically appropriate. Note: Prozac Weekly and Sarafem both have alternative formulations available on the Uniform Formulary (fluoxetine immediate release).
2. The patient has previously responded to a non-formulary antidepressant, and changing to a formulary antidepressant would incur unacceptable risk (e.g., the patient is currently stabilized on therapy with a non-formulary antidepressant and changing to a formulary antidepressant would present a risk of destabilization).

Paxil CR - the non-formulary cost share for the nonformulary paroxetine product Paxil CR may be reduced to the formulary cost share if:

1. Use of the formulary product (paroxetine immediate release) is contraindicated (e.g., hypersensitivity to a dye or other inert ingredient), treatment with Paxil CR is not contraindicated, and use of other formulary antidepressants is not clinically appropriate.
2. The patient has previously responded to Paxil CR, and changing to the formulary product (paroxetine immediate release) or another formulary antidepressant would incur unacceptable risk (e.g., the patient is currently stabilized on therapy with Paxil CR and changing to a formulary antidepressant would present a risk of destabilization).
3. No other formulary antidepressant is clinically appropriate (the patient requires treatment with paroxetine) and the patient is likely to experience intolerable adverse effects when starting therapy with paroxetine immediate release due to predisposing factors for nausea (e.g., chemotherapy, GI disorder). Note: Paroxetine controlled release appears to result in significantly lower rates of nausea (14% vs. 23%, based on clinical trials) in the first week after starting therapy, compared to paroxetine immediate release. This advantage does not appear to persist after the second or third week, when nausea rates decline overall.

Lexapro - the non-formulary cost share for Lexapro may be reduced to the formulary cost share if the patient meets any of the following criteria:

1. Use of other formulary SSRIs is contraindicated (e.g., hypersensitivity to a dye or other inert ingredient) and treatment with other formulary antidepressants is not clinically appropriate.
2. The patient has previously responded to Lexapro, and changing to a formulary SSRI would incur unacceptable risk (e.g., the patient is currently stabilized on therapy with Lexapro and changing to a formulary SSRI would present a risk of destabilization).
3. The patient has previously tried at least two other SSRIs and could not tolerate the adverse effects, and treatment with other formulary antidepressants is not clinically appropriate.
4. The patient has previously failed adequate trials of at least two other SSRIs, without response or remission, and treatment with other formulary antidepressants is not clinically appropriate. Note: an adequate trial is generally considered to be at least 6 weeks in duration, due to the delay in achieving maximal benefit.

Aplenzin - the non-formulary cost share for Aplenzin may be reduced to the formulary cost share if the patient meets any of the following criteria:

1. Use of other formulary bupropion agents is contraindicated (e.g., hypersensitivity to a dye or other inert ingredient) and treatment with other formulary antidepressants is not clinically appropriate.

Cymbalta - the non-formulary cost share for Cymbalta may be reduced to the formulary cost share if the patient meets any of the following criteria:

1. Use of the formulary SNRI (venlafaxine) is contraindicated (e.g., hypersensitivity to a dye or other inert ingredient) and use of any other formulary antidepressant is not clinically appropriate.
2. The patient has previously responded to Cymbalta, and changing to a formulary medication would incur unacceptable risk (e.g., the patient is currently stabilized on therapy with Cymbalta and changing to a formulary medication would present a risk of destabilization).
3. The patient is being treated for depression, generalized anxiety disorder, or another psychiatric condition, requires treatment with an SNRI (e.g., due to failure of SSRI therapy), and has failed an adequate trial of venlafaxine. Note: an adequate trial is generally considered to be at least 6 weeks in duration, due to the delay in achieving maximal benefit.
4. requires treatment with an SNRI (e.g., due to failure of SSRI therapy), and has been unable to tolerate venlafaxine.
5. The patient is being treated for neuropathic pain AND the patient meets one of the following criteria:

- has failed adequate trials of at least one medication from at least two of the following four drug classes: tricyclic antidepressants (e.g., amitriptyline, nortriptyline), SNRI antidepressants (e.g., gabapentin), or opioids (e.g., tramadol). Note: an adequate trial is, in general, considered to be at least 6 weeks in duration.
 - has tried and been unable to tolerate at least one medication from at least two of the following four drug classes: tricyclic antidepressants (e.g., amitriptyline, nortriptyline), SNRI antidepressants (venlafaxine), anticonvulsants (e.g., gabapentin), or opioids (e.g., tramadol).
 - it is clinically inappropriate (e.g., due to contraindications) for the patient to receive treatment with at least two of the following four drug classes: tricyclic antidepressants (e.g., amitriptyline, nortriptyline), SNRI antidepressants (venlafaxine), anticonvulsants (e.g., gabapentin), or opioids (e.g., tramadol).
6. The patient has been diagnosed with fibromyalgia AND the patient meets one of the following criteria:
- has failed adequate trials of pregabalin (Lyrica) AND at least one of the following medications: tricyclic antidepressants (e.g., amitriptyline) or cyclobenzaprine.
 - has tried and been unable to tolerate pregabalin (Lyrica) AND at least one of the following medications: tricyclic antidepressants (e.g., amitriptyline) or cyclobenzaprine.
 - it is clinically inappropriate (e.g., due to contraindications) for the patient to receive treatment with pregabalin (Lyrica) AND at least one of the following medications: tricyclic antidepressants (e.g., amitriptyline) or cyclobenzaprine.

Criteria recommended by the DoD Pharmacy & Therapeutics Committee at the August 2008 meeting and approved by the Director, TMA on 24 October 2008. Document was updated based on criteria recommended at the November 2005 and January 2006 meetings, and approved by the Director, TMA. For more information, please see the November 2005, August 2007, August 2008 and November, 2009 [DoD P&T Committee minutes](#).

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TRICARE Pharmacy Program Medical Necessity Form for Paxil CR, Prozac Weekly, and Sarafem

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This form applies to the TRICARE Pharmacy Program (TPharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- Formulary alternatives for these medications include: bupropion HCl immediate-/sustained-/extended-release (Wellbutrin/Wellbutrin SR/Wellbutrin XL), fluoxetine (Prozac), paroxetine immediate-release (Paxil), citalopram (Celexa), sertraline (Zoloft), venlafaxine immediate-release/Effexor XR/venlafaxine ER, mirtazapine, and nefazodone.
- Paxil CR/paroxetine CR, Prozac Weekly, and Sarafem are non-formulary, but available to most beneficiaries at the non-formulary cost share. Other non-formulary antidepressants are Aplenzin, Cymbalta, Lexapro, and Pristiq.
- You do **NOT** need to complete this form in order for non-active duty beneficiaries (spouses, dependents, and retirees) to obtain non-formulary medications at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of a non-formulary medication instead of a formulary medication is medically necessary. If a non-formulary medication is determined to be medically necessary, non-active duty beneficiaries may obtain it at the formulary cost share.
- Active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary. There is no cost share for active duty service members at any DoD pharmacy point of service.

MAIL ORDER and RETAIL	<ul style="list-style-type: none"> The provider may call: 1-866-684-4488 or the completed form may be faxed to: 1-866-684-4477 The patient may attach the completed form to the prescription and mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954 or email the form only to: TpharmPA@express-scripts.com 	MTF	<ul style="list-style-type: none"> Non-formulary medications are available at MTFs only if both of the following are met: <ul style="list-style-type: none"> The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF. The non-formulary medication is determined to be medically necessary. Please contact your local MTF for more information. There are no cost shares at MTFs.
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Step 1	Please complete patient and physician information (please print) Patient Name: _____ Physician Name: _____ Address: _____ Address: _____ Sponsor ID #: _____ Phone #: _____ Date of Birth: _____ Secure Fax #: _____
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Step 2	Paxil CR (paroxetine controlled-release) Please explain why the patient cannot be treated with any of the formulary agents listed below, including the formulary version of this product (paroxetine immediate-release). A specific explanation is required for each formulary agent. <table border="1" style="width: 100%;"> <thead> <tr> <th>Formulary Agent</th> <th>Reason</th> <th>Explanation</th> </tr> </thead> <tbody> <tr> <td>paroxetine immediate-release</td> <td>1 2 3 4 5</td> <td></td> </tr> <tr> <td>citalopram</td> <td>1 2 3 4 5</td> <td></td> </tr> <tr> <td>fluoxetine</td> <td>1 2 3 4 5</td> <td></td> </tr> <tr> <td>sertraline</td> <td>1 2 3 4 5</td> <td></td> </tr> </tbody> </table> <ol style="list-style-type: none"> The formulary agent is contraindicated (e.g., due to hypersensitivity to the agent or an inert ingredient). The patient has experienced significant adverse effects with the formulary agent, but is expected to tolerate Paxil CR. An adequate trial of the formulary agent resulted in therapeutic failure, but the patient is expected to respond to Paxil CR. The patient has previously responded to Paxil CR and changing to a formulary agent would incur unacceptable risk (e.g., risk of destabilization). The patient is likely to experience intolerable adverse effects when starting therapy with paroxetine immediate release due to predisposing factors for nausea (e.g., chemotherapy, GI disorder). 	Formulary Agent	Reason	Explanation	paroxetine immediate-release	1 2 3 4 5		citalopram	1 2 3 4 5		fluoxetine	1 2 3 4 5		sertraline	1 2 3 4 5	
Formulary Agent	Reason	Explanation														
paroxetine immediate-release	1 2 3 4 5															
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fluoxetine	1 2 3 4 5															
sertraline	1 2 3 4 5															

Questions for Prozac Weekly and Sarafem are on Page 2. For all products, please sign and date at the bottom of Page 2 (Step 3).

TRICARE Pharmacy Program Medical Necessity Form for Paxil CR, Prozac Weekly, and Sarafem

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**Step
2**

Prozac Weekly (fluoxetine 90-mg capsules for weekly dosing for the maintenance of response in depression)

Please explain why the patient cannot be treated with any of the formulary agents listed below, including the formulary version of this product (generic fluoxetine given daily). A specific explanation is required for each formulary agent.

Formulary Agent	Reason	Explanation
fluoxetine	1 2 3 4	
citalopram	1 2 3 4	
paroxetine immediate-release	1 2 3 4	
sertraline	1 2 3 4	

1. The formulary agent is contraindicated (e.g., due to hypersensitivity to the agent or an inert ingredient).
2. The patient has experienced significant adverse effects with the formulary agent, but is expected to tolerate Prozac Weekly.
3. An adequate trial of the formulary agent resulted in therapeutic failure, but the patient is expected to respond to Prozac Weekly.
4. The patient has previously responded to Prozac Weekly and changing to a formulary agent would incur unacceptable risk (e.g., risk of destabilization).

Sarafem (fluoxetine 10- or 20-mg capsules in special packaging for treatment of premenstrual dysphoric disorder [PMDD])

Please explain why the patient cannot be treated with the formulary version of this product or with sertraline, which is also FDA-approved for the treatment of PMDD. A specific explanation is required for each formulary agent.

Formulary Agent	Reason	Explanation
fluoxetine	1 2 3 4	
sertraline	1 2 3 4	

1. The formulary agent is contraindicated (e.g., due to hypersensitivity to the agent or an inert ingredient).
2. The patient has experienced significant adverse effects with the formulary agent, but is expected to tolerate Sarafem.
3. An adequate trial of the formulary agent resulted in therapeutic failure, but the patient is expected to respond to Sarafem.
4. The patient has previously responded to Sarafem and changing to a formulary agent would incur unacceptable risk (e.g., risk of destabilization).

**Step
3**

I certify the above is correct and accurate to the best of my knowledge. Please sign and date:

Prescriber Signature

Date

Latest revision: September 28, 2011